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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/636,072

08/06/2003

James Lousararian

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EXAMINER

YABUT, DIANE D

ART UNIT

PAPER NUMBER

3734

NOTIFICATION DATE

DELIVERY MODE

01/23/2009

ELECTRONIC

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

rs.vasciplegal@medtronic.com

## Office Action Summary

**Application No.**

10/636,072

**Applicant(s)**

LOUSARARIAN ET AL.

**Examiner**

DIANE YABUT

**Art Unit**

3734

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period **will** apply and **will** expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply **will**, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 21 October 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1,3-17 and 48-50 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,3-17 and 48-50 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                     | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date: _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date: _____   | 6) <input type="checkbox"/> Other: _____                          |

### DETAILED ACTION

This action is in response to applicant's amendment received on 10/21/2008.

The examiner acknowledges the amendments made to the claims.

### *Claim Rejections - 35 USC § 103*

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. Claims 1, 3-8, 48, 50 are rejected under 35 U.S.C. 103(a) as being unpatentable over **Cummins** (U.S. Patent No. **7,008,435**) in view of Williamson, IV et al., hereinafter **Williamson** (U.S. Patent No. **5,972,004**).

Claims 1, 3-8, 48, 50: Cummins discloses an individual staple **10** having a proximal end adapted for individual attachment to a single-staple delivery and closure device, the staple having a plurality of distally extending prongs commonly connected to the proximal end at a crown and having tissue-piercing distal tips with sufficient stiffness to pierce tissue solely in response to a distal force applied at the proximal end, and a pledget **12** being pre-attached to the staple (before the staple engages tissue) and being embraced by the prongs, the pledget having preformed edges or peripheral notches **16** configured to be frictionally engaged by and between the prongs to capture and retain the pledget to the staple and to enable the combined staple and attached

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pledget to be advanced together by a single-staple delivery device, whereby when the prongs of the staple are engaged with tissue, the pledget will be disposed and retained (Figures 1-6). The pledget may have a plurality of peripherally extending tabs configured to be received between said plurality of prongs (tabs on either side of edges or slots **16** in Figure 1) or The pledget comprises a bioasorbable woven or non-woven fabric material, and a polyester or polymer sheet (col. 3, lines 41-44).

Cummins does not expressly disclose the pledget being carried by the staple before and during delivery of the delivery and closure device.

Williamson teaches a pledget **P** that may be placed on a staple ("fastener") before being placed on the tool for delivery (Figures 4 and 24, col. 12, lines 53-59). It would have been obvious to one of ordinary skill in the art at the time of invention to provide a staple that carries a pledget, as taught by Williamson, to Cummins in order to ensure and maintain a secure engagement between the two elements when fastened against tissue.

3. Claims 9-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over **Cummins** (U.S. Patent No. **7,008,435**) in view of **Williamson** (U.S. Patent No. **5,972,004**), as applied to claim 1 above, and further in view of **Dalessandro** (U.S. Patent No. **6,273,897**).

Claims 9-17: Cummins and Williamson disclose the claimed device, except for the pledget having a physiologically active agent adapted to be released over a predetermined time interval or comprising a coating or being impregnated in the

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pledget, or being an anti-microbial/antiseptic agent, or being an agent that inhibits intraluminal clotting or promotes extraluminal clotting.

Dalessandro teaches a bioabsorbable pledget (or “buttress”) **52** containing physiologically active agents that are released over a predetermined time interval, anti-microbial or anti-septic agents, agents that inhibit intraluminal clotting or promote extraluminal clotting, or agents that comprise a coating or are impregnated in said pledget (Figures 4-6, col. 5, lines 24 to col. 7, line 55). It would have been obvious to one of ordinary skill in the art at the time of invention to provide a pledget comprising the above materials and agents, as taught by Dalessandro, to Cummins and Williamson since they are well known in the art for their biocompatibility and other benefits that promote healing.

4. Claim 49 is rejected under 35 U.S.C. 103(a) as being unpatentable over **Cummins** (U.S. Patent No. **7,008,435**) in view of **Williamson** (U.S. Patent No. **5,972,004**), as applied to claim 1 above, and further in view of **Ginn** (U.S. Patent No. **6,277,140**).

Claim 49: Cummins and Williamson disclose the claimed device, except for the crown including distally extending tabs or webs adapted to bear against the pledget.

Ginn teaches a staple **62** having four prongs **76** and being commonly connected at a crown **70** including distally extending tabs or webs (near **74**) adapted to bear against a pledget (Figure 28). It would have been obvious to one of ordinary skill in the

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art at the time of invention to provide the distally extending tabs or webs, as taught by Ginn, to Cummins and Williamson in order to create a secure engagement between the pledget and the staple.

### ***Response to Arguments***

5. Applicant's arguments filed 10/21/2008 have been fully considered but they are not persuasive.

6. Applicant argues that Cummins does not disclose a staple closable solely by manipulation of its proximal end since no particular mechanism is disclosed in which the staple prongs can be closed by merely by force applied to the proximal end of the staple. However, no particular mechanism is recited, and the staple 10 of Cummins is capable of being closed by a mechanism that solely manipulates its proximal end, such as a pusher member that applies a distal force to the proximal end until it engages an anvil that deforms the prongs, and therefore it reads on this limitation. Cummins also contemplates a staple-firing mechanism that bends the staple by driving the staple towards a free end, or distally, which inherently suggests manipulating the proximal end of the staple (col. 3, lines 61-65).

7. Applicant also argues that neither Cummins nor Williamson teaches a pledget being directly and securely frictionally engaged by and between the prongs of the staple before and during delivery of the device, or the pledget and staple being pre-attached and advanced together during delivery. However, Williamson teaches, as clearly seen

in Figures 24-26, that the staple and pledget are directly and securely frictionally engaged by and between the prongs of the staple before and during delivery of the device, and that it is well known in the art to provide a pledget and staple unit to attach to tissue (col. 12, lines 53-59).

8. In response to applicant's argument that there is no suggestion to combine the references and that the combination is improper because there is no resolution or articulation of the level of skill that was applied, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. In this case, and as maintained above, the motivation of having the staple and pledget being directly and securely engaged before and during advancement into tissue is to ensure and maintain a secure engagement between the two elements to facilitate closure.

### ***Conclusion***

9. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the

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shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to DIANE YABUT whose telephone number is (571)272-6831. The examiner can normally be reached on M-F: 9AM-4PM EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Todd Manahan can be reached on (571) 272-4713. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Diane Yabut/  
Examiner, Art Unit 3734



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/Todd E Manahan/

Supervisory Patent Examiner, Art Unit 3731